

REMARKS

Claims 1-28, 115-122, 127, 128, 132 and 133 are currently pending. Claims 29-144, 123-126, 129-131 and 134-137 have been withdrawn by the examiner as, in the examiner's opinion, being drawn to separate and distinct invention(s) from that of pending claims.

It is noted that claims 117-122, 127, 128 and 133, which the examiner initially placed in Group I, applicants' elected group, in fact depend from independent claims 29 (117, 118, 133), which is in the examiner's Group II, 57 (119, 120), which is in the examiner's Group III, 62 (121, 122), which is also in the examiner's Group III and 96 (127, 128), which is in the examiner's Group VIII. If the examiner agrees, he may wish to withdraw these claims from examination.

35 U.S.C. § 102 rejection of claims 1-21

The examiner has maintained the prior rejection of claims 1-21 under §102 as being anticipated by Webster, et al., U.S. Pat. No. 6,123,699, iterating virtually verbatim the rationale previously set forth. That is, the examiner states that Webster discloses a deflectable catheter assembly comprising: a catheter shaft (interior of element 91); a tendon (31) disposed within a first lumen of said catheter shaft, said first lumen being approximately centrally located within said catheter shaft at said catheter proximal section (as in figure 8 for example) and said first lumen located off-center of said catheter shaft at said catheter distal section (as in figure 6A and 6B, said tendon being able to deflect said catheter distal section when being pulled on (as in figures 1 and 7); and a catheter handle (14) coupled to said catheter shaft, said catheter handle including a first control mechanism (63 for example) to control said tendon, and slip bands (33). The examiner goes on to assert that Webster also comprises a needle "(not shown but inherent, see paragraphs beginning at column 3, line 16)" or a plurality of needles, disposed within said lumen of said catheter shaft also "(not shown but in fifth lumen and an inherent feature of Webster, also concerning claims 10-11)."

The examiner then states that with regard to claims 5 and 6, Webster further comprises an axial spine (91 or 92) disposed around and over a first section of said tendon, said first section being substantially aligned with said catheter proximal section, said axial spine to resist axial compression along said catheter proximal section (see figure 11), and a flexible tendon sheath (95) coupling to said axial spine, said flexible

tendon sheath extending a second section of said tendon and said second section being substantially aligned with said catheter distal section (see figures 1-14).

Finally, with regard to claim 8 and 9, the examiner states that Webster discloses: a tip electrode (29) located at the tip of said catheter distal section and coupled to a conductive lead that extends out of said catheter shaft and at least one additional electrode (28); a deflectable catheter fully capable of all flexibility requirements in claims 16-17 (see figure 7); and a pre-shaped guide sheath (92, 91) disposed around said catheter shaft that is fully capable of satisfying all functional, structural, and operational limits of the claims as written.

With regard to applicants previous response to the above rejection, the examiner states that he is taking the position that the word "approximately" means "to come near, approach closely to, or similar to" and, therefore, the limitation in current claim 1 that the catheter assembly comprise "a tendon disposed within a first lumen of said catheter shaft, said first lumen being approximately centrally located within said catheter shaft," does not require the lumen to be exactly defining a central axis of the catheter. The examiner further states that he is reading "centrally" as meaning "forming the center; or in, at or near the center." Within this reading, the examiner takes the position that the first lumen of Webster is approximately centrally located and therefore Webster anticipates the current invention or renders it obvious when combined with Edwards, U.S. Pat. No. 6,254,598.

Applicants traverse.

Applicants' response

Webster could not be more different from the current invention. One need look no further than the Abstract to confirm such. For example, the Abstract reads:

The catheter body may have a central lumen, and four off-axis lumens symmetrically positioned about the central lumen. A puller wire [which as stated in applicants' previous response, the examiner characterizes as a "tendon" to relate it to the current invention] extends from the central handle through each off-axis lumen and is anchored to the tip section at a selected location.

Then, at Col. 4, lines 49-52, it is stated that:

With reference to Fig. 2, the catheter body 12 comprises an elongated tubular construction having four outer lumens 17

and a central lumen 18. The outer lumens 17 are arranged symmetrically into quadrants about the central lumen 18.

Further, at Col. 5, lines 50-52, it is stated that:

A puller wire 31 extends from the central control handle 14 through each of the outer lumens 17 in the catheter body 12 and into aligned outer lumen 23 in the tip section 13.

Moreover, at Col. 7, lines 42-48, it is stated that:

It is understood that each of the four puller wires 31 may be anchored at the same location along the length of the catheter tip section 13 ... Alternatively the puller wires 31 may be anchored at three or four different locations.

In addition, at Col. 9, lines 57 to 60, it is stated that:

To prevent simultaneous movement of diametrically opposed puller wires 31 and yet allow for simultaneous movement of any two adjacent puller wires, there is provided a moveable stop 81 within the handle.

And finally, at Col 10, lines 12-13, it is stated that:

In the embodiment described above, the central lumen is used for passage of electrode lead wires.

The examiner is reminded that, to anticipate a claim, a putative prior art reference, when considered as a whole, must disclose each and every element of that claim (Medichem, S. A. v. Rolado, S. L., 437 F.3d 1157 (Fed. Cir. 2006)). When considered as a whole, nothing could be clearer than the stark differences between Webster and the current invention. As the above quotes from Webster attest – and all of the figures in Webster corroborate, Webster's catheter demands four lumens disposed along two diameters of the tubular construction that are at right angles from one another so as to form symmetrical quadrants. Regardless of how the examiner chooses to interpret "approximately" or "centrally" in claim 1 of the present invention, which incidentally applicants do not necessarily agree with, it is utterly impossible to interpret Webster's "four outer lumens" as being "approximately centrally located" so as to read on the current invention, which simply has "a tendon disposed within a first lumen ... approximately centrally located within said catheter...".

Since claims 2-21 depend from claim 1, they include all of the limitations of claim 1 including, of course, the approximately centrally located lumen containing the tendon ("puller wire" in Webster's terminology), a feature that is absent in Webster.

Based on the above, Webster does not and cannot anticipate any of claims 1-21 of the current invention. The examiner is requested to reconsider and withdraw the rejection.

35 U.S.C. § 103 rejection of claims 22-28

The examiner has likewise maintained the previous § 103 rejection of claims 22-28 as being unpatentable over Webster in view of Edwards, et al., U.S. Pat. No. 6,254,598. That is, the examiner admits that Webster is silent as to the medical device comprising a needle or a plurality of needles with at least one inflatable balloon coupling to said plurality of needles (and with a divergent angle), tube mechanism with needle stop disposed within a lumen of a catheter shaft being extendable from and retractable into the catheter distal section and a control in the catheter handle. In the examiner's view, however, Edwards discloses these elements and the examiner is further of the opinion that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Webster catheter with the needles/balloon mechanism of Edwards since "such a modification would provide the catheter with the needles/balloon mechanism for providing a unique and direct medical treatment operation."

Applicants traverse.

Applicant's response

Since, for the reasons discussed above, Webster has no bearing whatever on the current invention and since Edwards as explicated by the examiner adds nothing to Webster to overcome Webster's deficiencies, the combination of Webster and Edwards cannot and does not render the current invention obvious. The examiner is requested to withdraw the rejection.

35 U.S.C. § 103 rejection of claims 115-122, 127, 128, 132 and 133

Finally, the examiner has also iterated the previously promulgated rejection of claims 115-122, 127, 128, 132 and 133 under § 103(a) as being unpatentable over Webster in view of Edwards and further in view of Balbierz, U.S. Pat. No. 6,770,070. Here, in the examiner's view, Webster/Edwards discloses the claimed invention except

for using and coupling pressure sensors to a needle. The examiner, however, is of the opinion that Balbierz provides this teaching and that it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the Webster catheter as modified by Edwards to use the Balbierz needle-coupled pressure sensors since such a modification would provide the catheter with using and coupling pressure sensors to a needle for providing specific diagnostic feedback mechanism to the catheter.

The examiner admits that, with regard to claims 132 and 133, Webster/Edwards is silent as to the needle being made of a polymer. The examiner argues, however, that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the needle of a polymer material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Applicants traverse.

Applicants' response

Since, for the reasons discussed above, Webster has no bearing whatever on the current invention and since neither Edwards nor Balbierz nor the combination of the two add anything to Webster to overcome Webster's deficiencies, the combination of Webster, Edwards and Balbierz cannot and does not render the current invention obvious.

With regard to the examiner's statement that it would have been obvious to one skilled in the art to simply make a needle of a polymer, applicants in particular traverse. The examiner is requested to provide objective evidence corroborating this entirely unsupported and, in applicants' view, erroneous assertion.

Applicants request that the examiner reconsider and withdraw the rejection.

CONCLUSION

Applicant does not believe any fee is due with this response. If this is incorrect, the Commissioner is authorized to charge any fee(s) due to Squire Sanders and Dempsey, L.L.P. Deposit Account No. 07-1850.

If the examiner would like to discuss this response or any other aspect of the present application, he is invited to telephone the undersigned at (415) 954-0200.

Date: June 11, 2007

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Bernard F. Rose", with a large, stylized "R" at the end.

Bernard F. Rose

Reg. No. 42,112